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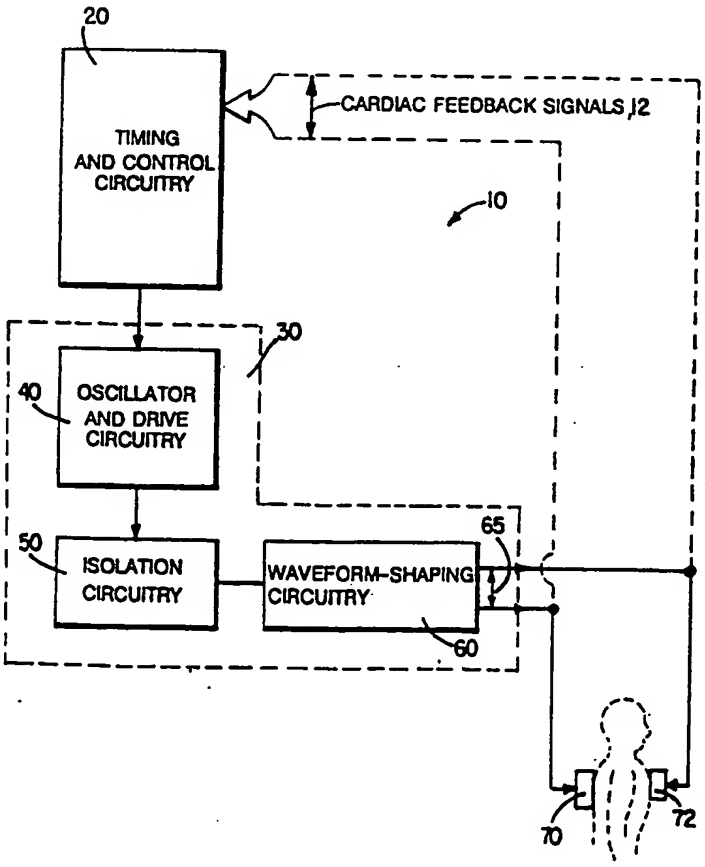
(57) Abstract

Method and apparatus for transcutaneously pacing the heart with pacing stimuli each of which comprises a series of individual pulses. The heart reacts to the series of pulses as if the series were one continuous pulse, whereas the pulse series produces skeletal muscle reactions that are similar to that which would be expected for individual pulses. The result is reduced stimulation of skeletal muscles and nerves, and less discomfort for the patient. Further reduction in stimulation of skeletal muscles and nerves can be achieved by providing a series of subthreshold initial pulses in each pacing stimulus, and by providing background stimuli occurring in the intervals between pacing stimuli. The apparatus includes timing and control circuitry (20), stimuli generating circuitry (30) connected to electrodes (70, 72).



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METHOD AND APPARATUS FOR TRANSCUTANEOUS CARDIAC PACING

Background of the Invention

This invention relates to electrically pacing the heart transcutaneously.

During transcutaneous, or external, electrical pacing of a patient's heart, electrical stimuli travel from the pacing apparatus' electrodes to the heart through the patient's skin and skeletal thorax muscles to stimulate the heart. Depending on the magnitude of the stimuli and the characteristics of a particular patient's skeletal muscles, the skeletal muscles may contract in response to the passage of the electrical stimuli through them. Similarly, the passage of the electrical pacing stimuli through the patient's skin may stimulate cutaneous nerves and muscles located near to the skin. This nerve stimulation and skeletal muscle contraction may feel uncomfortable to the patient, or even become painful enough to result in the patient's intolerance of extended transcutaneous heart pacing.

It has been shown (U.S. Patent No. 4,349,030) that the skeletal muscle contractions and cutaneous nerve stimulation associated with conventional transcutaneous heart pacing may be reduced by lengthening the duration of electrical pacing stimuli to greater than five milliseconds.

Summary of the Invention

In a first aspect, the invention features pacing stimuli each of which comprises a series of pulses. Each of the pulses is, by itself, incapable of causing a cardiac muscle contraction, but the series of pulses making up each pacing stimulus is capable, as a group, of causing such a contraction. The series of pulses tends

to produce less skeletal muscle stimulation than a continuous pulse, thus making extended transcutaneous pacing more bearable for a patient. In preferred embodiments, each pulse averages less than 0.5 msec (preferably less than 250 microseconds, and more preferably less than 50 microseconds); the duty cycle of the pulses (i.e., the percentage of time the pulse is on) is at least 20%, and more preferably at least 50%; and the amplitude of the pacing stimulus in the brief intervals between each pulse is below the minimum amplitude required for skeletal muscle stimulation if one were using a continuous pulse of the same duration as the pulse train (and is preferably substantially zero).

In a second aspect, the invention features reducing skeletal muscle stimulation during pacing by including in the pacing stimuli one or more pulses that have amplitudes below the threshold for skeletal muscle stimulation. Stimulation threshold is here defined as the minimum pulse amplitude required for stimulation if the pulse amplitude of a given pulse train remained constant for the duration of the pulse train. The subthreshold pulses tend to reduce the reaction of skeletal muscles to the above-threshold stimulus that follows them. In preferred embodiments, these subthreshold pulses are the initial pulses in a pacing stimulus itself comprising a series of pulses; the pacing stimulus extends for at least 5 msec (more preferably, at least 40 msec); and some, possibly all, of the subthreshold pulses, and possibly some of the above-threshold pulses, each has an amplitude that is greater than the amplitudes of the preceding pulses in the pacing stimulus.

The reduction in skeletal muscle stimulation is believed to result because the cardiac muscle reacts to the train of pulses as if it were one continuous pulse,

whereas at least some of the skeletal muscles react in a manner more akin to the way they would react to individual pulses. It is believed that this difference may result from a filtering of the pulse train as it passes through the chest wall, with the result that the cardiac muscle sees a continuous stimulus, whereas at least some of the skeletal muscles are exposed to the unfiltered, or less filtered, pulses, which, because of their short duration, produce less skeletal muscle stimulation. But whatever physiological actions are actually responsible, the result is that, at cardiac threshold (i.e. at a stimulus amplitude just high enough to cause cardiac contraction), the skeletal muscles are stimulated less by a train of pulses than by a continuous pulse.

In a third aspect, the invention features providing background stimuli in the intervals between pacing stimuli to reduce discomfort during pacing. In preferred embodiments, the background stimuli occur only in the intervals between the pacing stimuli; the background stimuli comprise pulses; the average amplitude of the background pulses is less than the average amplitude of the pacing stimuli; the average amplitude of the background pulses is less than 20 mA (more preferably less than 10 mA); and the duty cycle of the background pulses is less than 80% (more preferably less than 50%).

In a fourth aspect, the invention features an electrode for transcutaneous pacing in which there are two skin-contacting regions each insulated and spaced laterally from the other.

Other features and advantages of the invention will be apparent from the following description of a preferred embodiment and from the claims.

Description of the Preferred Embodiment

Fig. 1 is a block diagram of a pacing stimuli signal generator according to one embodiment of the invention.

Fig. 2 is an illustrative example of electrical stimuli produced by the signal generator of Fig. 1.

Figs. 3A and 3B are illustrative examples of electrical pacing stimuli produced by the signal generator of Fig. 1.

Fig. 4 are plotted characteristics, one for cardiac muscle and one for skeletal muscle and cutaneous nerves, relating a stimulating pulse's strength with the pulse's duration.

Fig. 5 is an example of an electrode configuration for applying the electrical stimuli of Fig. 2 to a patient.

Figs. 6A-6C are three illustrative examples of alternative pacing stimuli produced by the signal generator of Fig. 1.

Referring to Fig. 1, there is shown a signal generator 10 for generating electrical pacing stimuli 65 which are to be applied transcutaneously to a patient's heart. The signal generator's timing and control circuitry 20 can accept cardiac feedback signals 12 from the patient to initiate electrical pacing stimuli, or it can operate without such feedback (asynchronous pacing). The timing and control circuitry also sets the timing characteristics of the pacing stimuli, as discussed below. The timing and control circuitry 20 initiates the pacing stimuli by signaling the stimuli generating circuitry 30, which includes oscillator and drive circuitry 40, isolation circuitry 50, and waveform-shaping circuitry 60. Oscillator and drive circuitry 40 generates a stream of pulses that are processed by isolation circuitry 50, which isolates the signal generator's internal voltages from the patient, thereby

providing electrical hazard protection for the patient during the patient's exposure to the pacing stimuli 65.

Waveform-shaping circuitry 60 receives the isolation circuitry's pulse stream output and modifies signal characteristics of the pulse stream, e.g., pulse shape, polarity, and amplitude, to generate pacing stimuli 65 having user-specified signal parameters. At the signal generator's output, the pacing stimuli 65 are coupled to posterior and anterior electrodes 70, 72, which together externally deliver the electrical stimuli to the patient for transcutaneous pacing of the patient's heart.

Referring to Fig. 2, the signal generator's electrical pacing stimuli output 65 is composed of pacing stimuli 80 and background pulse trains 90. The pacing stimuli 80, comprising, for example, pacing pulse trains, are delivered to the patient to stimulate the patient's heart. The background pulse trains 90 are delivered to the patient in the intervals between the pacing pulse trains, when the heart is not being stimulated. Together, these pulse train stimuli provide effective transcutaneous stimulation of the heart with reduced patient discomfort.

Referring to Fig. 3A, the pacing pulse trains 80 each consist of a series of pulses, with each pulse having a time duration, or width, W_p, which may be different than the duration of the other pulses in the series.

Referring also to Fig. 4, there are shown characteristic curves for pulse stimuli, representing the relationship between a pulse's current amplitude, or strength, i, and a pulse's duration, t, for stimulating cardiac muscle and skeletal muscle. The duration, T_t, of each pacing pulse train 80 (Fig. 3) is chosen by considering these strength-duration curves. Each curve

delineates the minimum duration, t, which an electrical pulse stimulus having a given current amplitude, i, will require to stimulate a muscle. Stated another way, given a pulse amplitude, i, a muscle will not be stimulated unless the pulse duration, t, is on, or to the right of, the corresponding curve. Two different stimulus points lying on the strength-duration curve for a muscle, like points A and B on the cardiac muscle curve, will equally effectively stimulate that muscle.

A minimum pulse amplitude, or rheobase (Ri_c for cardiac muscle and Ri_s for skeletal muscle), defines the smallest pulse amplitude that will stimulate a muscle. Any stimulus having a current amplitude less than the rheobase will not stimulate a muscle, even if the pulse's duration is greater than the rheobase duration, called the utilization time, (Rt_c for cardiac muscle and Rt_s for skeletal muscle). Comparing the strength-duration curves of Fig. 4, the cardiac muscle's utilization time, Rt_c, which is greater than approximately 40 msec, is longer than that of skeletal muscle, having a utilization time Rt_s which is considerably less than 40 msec.

Given these utilization times for cardiac and skeletal muscle, a preferable range for the pacing pulse trains' durations T_t is selected with the following consideration. While any stimulus point on the cardiac strength-duration curve produces effective cardiac stimulation, stimulus points having lower current amplitudes tend to produce lower skeletal muscle stimulation than stimulus points having higher current amplitudes, for a given stimulus duration. Accordingly, a pulse stimulus having the characteristics of point A (close to the cardiac utilization time Rt_c) stimulates skeletal muscle less than a pulse stimulus having the characteristics of point B, but will stimulate the heart equally effectively. Therefore, by choosing a pulse

train duration around the same duration as the cardiac utilization time, the heart can be adequately stimulated by the pulse train while producing less skeletal muscle stimulation than would be produced by a pulse train of shorter duration and correspondingly higher pulse current amplitudes. The total time duration, T_t, of each pacing pulse train is therefore preferably at least 5 msec, or more preferably 20 msec, but may be of any duration sufficient to stimulate the heart. The maximum preferable pacing pulse train duration is limited to approximately 150 msec because of safety considerations for inducing cardiac fibrillation.

The pulse width W_p and pulse period T_p of each of the pulses in the pacing pulse trains are also selected based on a comparison of the strength-duration relationships for cardiac muscle and skeletal muscle (Fig. 4). As shown in Fig. 4, a minimum pulse duration, called the chronaxie (Ct_c for cardiac muscle and Ct_s for skeletal muscle), is the pulse duration corresponding to a stimulating pulse amplitude equal to twice the rheobase of a muscle. With a pulse stimulus having a duration shorter than the chronaxie, it becomes increasingly difficult to stimulate a corresponding muscle.

Considering the strength-duration curves of Fig. 4, the cardiac muscle's chronaxie Ct_c is approximately equal to 2 msec and the skeletal muscle's chronaxie Ct_s is approximately equal to 0.5 msec. A pulse stimulus of a duration shorter than the skeletal muscle chronaxie Ct_s, having, e.g., the duration of a pulse at point C, would therefore tend not to stimulate either cardiac muscle or skeletal muscle. However, a train of such pulses having suitably adjusted amplitudes and a pulse train duration T_t which is longer than the cardiac muscle chronaxie Ct_c, e.g., the stimulus duration of point A, effectively stimulates the heart as if the pulse trains

had been filtered by, e.g., the skeletal muscles, to produce a continuous pacing pulse.

Referring again to Fig. 3, based on this consideration, the pulse width W_p of each of the pacing pulses is selected to be less, preferably much less, than the skeletal muscle chronaxie Ct_s (0.5 msec). With pulses of such width, the skeletal muscles tend to be stimulated less than they would if the pacing pulse were a single continuous pulse, but the heart is stimulated as effectively as a continuous pulse. The pacing pulse width W_p for achieving this condition is preferably less than 100 microseconds, and most preferably less than 15 microseconds. Pulse widths of less than about 7 microseconds may produce a pacing pulse frequency which is high enough to cause tissue damage, and thus may need to be avoided. Given the selected pulse width W_p, the pacing pulse period T_p is selected to ensure adequate pacing stimulation, or capture, of the heart. The preferred pacing pulse duty cycle is 66%, but a lower duty cycle, e.g., 20%, or a variable duty cycle may be used, provided the given duty cycle is adequate to capture the heart. Generally speaking, the higher the duty cycle, the higher will be the effective filtered amplitude of the continuous pulse that influences the cardiac muscle.

A variation in the form of the pacing stimuli is shown in Fig. 3B. The amplitude, i_i, of the first pulse in each pacing pulse train has a subthreshold amplitude, i.e., the amplitude is below the minimum pulse amplitude required for stimulation if the pulse amplitude of a given pulse train remained constant for the duration of the pulse train. Each of the pulses following the initial pulse has an amplitude greater than that of the previous pulses, with some number of trailing pulses all having a maximum current amplitude, i_M. The value of

this maximum current amplitude i_M is selected, along with other pulse train characteristics, e.g., pulse train duration, to ensure capture of the heart. For example, a pulse train with a given number of pulses having a maximum current amplitude i_M may require a shorter duration to capture the heart than a pulse train with fewer pulses having a maximum current amplitude that is greater than i_M.

The use of initial, subthreshold pulses, followed by a series of pulses each having an amplitude that is greater than the amplitudes of the preceding pulses is intended to induce accommodation of the skeletal muscles to the pacing pulse train stimuli. Accommodation of a muscle is a physiological phenomenon which can be induced by gradually, rather than abruptly, exposing a muscle to a stimulus amplitude, whereby the stimulating threshold of the muscle is increased beyond the magnitude of the applied stimulus. An accommodated muscle or nerve requires a higher than normal stimulus magnitude to be effectively stimulated, and may even reject stimulation altogether for any magnitude of stimulus increase.

Given the physiological differences between cardiac muscle and skeletal muscle, the amplitudes of the pulses in the pacing pulse train are selected to cause accommodation of skeletal muscles but not to cause accommodation of cardiac muscle. By simultaneously achieving these conditions, the pacing pulse trains effectively stimulate the heart but tend to decrease the skeletal muscle stimulation typically associated with the transcutaneous cardiac muscle stimulation.

Referring again to Fig. 2, the background pulse trains 90 are provided during the intervals between the pacing stimuli. Each background pulse train comprises a series of pulses, with the amplitudes of the pulses alternating between a positive amplitude, i_B, and a

negative amplitude, $-i_B$, in a biphasic fashion. While Fig. 2 shows each of the background pulses having the same amplitude magnitude, each of the pulses may have differing amplitudes. The magnitude of the alternating amplitudes, $|i_B|$, is preferably below the minimum current amplitude which a pulse, having the width W_B, would require to stimulate the skeletal muscles.

During the interval between each background pulse, the background pulse train has an amplitude, e.g., zero amplitude, that is below the current amplitude required to stimulate skeletal muscle. Given a particularly chosen amplitude between pulses, the pulse width W_B and period T_B of the background pulses are chosen to fulfill two criteria: 1. The duty cycle ($100 \times 2W_B/T_B$) of the background pulses is preferably less than 80%, or more preferably less than 50%, for providing a low average current; and 2. For a given i_B, T_B, and W_B combination, the skeletal muscles are minimally stimulated. The average current (i_B x duty cycle) is preferably less than 20 mA, and more preferably less than 10 mA.

The subthreshold stimulus from the background pulse trains 90 tends to reduce the pacing pulse trains' stimulation of the skeletal muscles, possibly through accommodation of those muscles. That is, by adding the background pulse trains, the discomfort from stimulation of skeletal muscle during cardiac pacing is less than it would be without the background pulses (when the pacing stimuli are at threshold).

Given the physiological differences between cardiac muscle and skeletal muscle, the background pulse characteristics are accordingly selected to enhance accommodation of the skeletal muscles while discouraging accommodation of the cardiac muscle. Preferably, the background pulse characteristics are selected to induce a level of skeletal muscle accommodation which increases

the muscle stimulation threshold above the largest pacing pulse train stimuli amplitude. The background pulse trains 90, together with the pacing pulse trains 80, thereby tend to produce reduced stimulation of the skeletal muscles while simultaneously achieving effective stimulation of the heart.

The background pulse trains and pacing pulse trains also decrease the cutaneous nerve stimulation associated with transcutaneous cardiac pacing. Because the skeletal muscles and cutaneous nerves have similar chronaxies (Fig. 4), the cutaneous nerves, like skeletal muscles, tend to be stimulated less by the pulses in the pacing pulse trains than they would if the pacing pulse were a single continuous pulse. Furthermore, the background pulse train characteristics selected to produce accommodation of skeletal muscles accordingly produce accommodation of cutaneous nerves.

Referring again to Fig. 1, the signal generator's waveform-shaping circuitry 60 modifies the stream of pulses generated by the oscillator circuitry 40 to create and distinguish the pacing and background pulse trains in the pacing stimuli 65. This modification may require amplitude or polarity adjustment for the particular electrodes used with the signal generator, as discussed below. The timing and control circuitry 20 provides further fine adjustment of the pacing pulse train characteristics, for example, pulse shape. Both the waveform-shaping circuitry 60 and the timing and control circuitry 20 may be programmed to include or omit any or more of the electrical signal characteristics discussed above.

A variety of electrode structures may be used to deliver the pacing stimuli. The pacing stimuli are passed through the patient's thorax from the posterior electrode to the anterior electrode.

In view of the reduced skeletal muscle and cutaneous nerve stimulation that is achieved by the pacing and background stimuli, the contribution of the electrode configuration to stimulation reduction may be less important. Thus, conventional noninvasive pacing electrodes with nonmetallic skin-contacting members, such as those disclosed in U.S. Patent No. 4,349,030, or as sold by R-2, of Morton Grove, Illinois, Physio-Control Corporation, of Redmond, Washington, or ZMI Corporation, of Woburn, Massachusetts, are suitable for delivering the pacing pulse trains. Alternatively, electrodes having metallic skin-contacting members may be adapted to deliver the pacing stimuli.

Another suitable electrode configuration is shown in Fig. 5. The anterior electrode 72 and posterior electrode 70 are adapted to deliver the pacing stimuli 65 from the signal generator 10 to a patient. A variety of electrode structures may be adequately used to achieve this function. Preferably, the electrodes are configured so that pacing pulse trains are delivered through the skin and skeletal muscles to the heart, whereas background pulse trains, if existent, are delivered only to the skin and skeletal muscles, and not to the heart. This electrode configuration ensures that cardiac fibrillation will not be induced by the background pulse trains.

As shown in Fig. 5, in this configuration, the electrodes 70, 72 are divided into central, isolated regions 70a, 72a, and surrounding annular regions 70b, 72b. Each of the central regions is separated from its corresponding annular region by a distance which is adequate to provide electrical isolation between the two regions, e.g., at least one-quarter inch. The lateral region within this separating distance may be filled with

an adhesive to act as an insulating material between the inner and outer electrode regions.

During delivery of a pacing pulse train, or the "pacing period," the stimuli are passed through the patient's thorax from the posterior electrode's central region 70a to the anterior electrode's central region 72a. During delivery of a background pulse train, or the "background period," the pacing stimuli never pass through the patient, but instead pass between the central and annular regions of each electrode, as shown in Fig. 5. The polarity of, or direction in which, the background stimuli are applied to the patient through the electrodes may be suitably altered without decreasing the effectiveness of the pacing stimuli for pacing the patient's heart. If no background pulse trains are present, the entire stimuli may pass through the patient's thorax from one central region 70a (anode) to the other central region 72a (cathode).

Other embodiments of the invention are within the claims.

For example, referring to Fig. 6A, the pacing pulse train could have an initial pulse 81 with a maximum amplitude i_M, followed by a series of pulses which each has an amplitude that is less than the amplitudes of all preceding pulses. As shown in Fig. 6B, the pacing pulse train could have an initial portion 100 of subthreshold pulses, all of an equal amplitude, followed by a portion 105 of above-threshold pulses, all of an equal amplitude. The initial portion 100 of subthreshold pulses may include a second portion of subthreshold pulses, all of a second, equal amplitude. Alternatively, as shown in Fig. 6C, the pacing pulse train could have alternating subthreshold pulses 110 and above threshold pulses 120. Another variation for achieving the subthreshold pulses is to vary the duration of the pulses; using shorter

durations for the subthreshold pulses, and longer durations for the above-threshold pulses. Given any pulse combination in a pacing pulse train, the pulses in a train could have non-rectangular shapes, e.g., triangular, exponential, or rounded. The duty cycle and duration of pulses can be varied within the pulse train (e.g., there could be brief gaps in the sequence of pulses).

The background pulses could also be used with conventional continuous pacing pulses, and could be applied continuously (even during the pacing stimuli). The background pulses could be monophasic. Individual background pulses could have non-rectangular shapes, e.g., triangular, exponential, or rounded. The amplitude, duration, and duty cycle of the background pulses could vary over time. Gaps could be present in the train of background pulses.

What is claimed is:

Claims

1. Apparatus for transcutaneously pacing the heart at a pacing rate, the apparatus comprising

stimuli generating circuitry for generating electrical stimuli, and

electrodes connected to the output of the stimuli generating circuitry for delivering the electrical stimuli to the patient,

wherein said electrical stimuli include pacing stimuli delivered at the pacing rate, each pacing stimulus comprising a series of individual pulses.

2. The apparatus of claim 1 wherein each series of pulses is capable, as a group, of causing a contraction of the heart, but each individual pulse is incapable, by itself, of causing such a contraction.

3. The apparatus of claim 1 wherein said series of pulses extends for a duration of at least 5 msec.

4. The apparatus of claim 1 wherein the duration of the individual pacing pulses averages less than 0.5 msec.

5. The apparatus of claim 4 wherein said average pulse duration is less than 250 microseconds.

6. The apparatus of claim 5 wherein said average pulse duration is less than 50 microseconds.

7. The apparatus of either of claims 4, 5, or 6 wherein the duty cycle of said individual pulses is greater than 20%.

8. The apparatus of claim 7 wherein the duty cycle of said individual pulses is greater than 50%.

9. The apparatus of claim 1 wherein the amplitude of said pacing stimulus in the interval between individual pulses is less than the threshold amplitude for stimulating cardiac muscle.

10. The apparatus of claim 7 wherein the average amplitudes of said series of individual pacing pulses rise from a first amplitude to a second amplitude.

11. The apparatus of claim 10 wherein said first amplitude is less than the threshold for stimulation of skeletal muscle.

12. The apparatus of claim 11 wherein said second amplitude is reached in not less than 2 pulses.

13. Apparatus for transcutaneously pacing the heart at a pacing rate, the apparatus comprising

stimuli generating circuitry for generating electrical stimuli, and

electrodes connected to the output of the stimuli generating circuitry for delivering the electrical stimuli to the patient,

wherein said electrical stimuli include pacing stimuli delivered at the pacing rate, each pacing stimulus comprising a plurality of pulses, with at least the initial pulse in each stimulus having an amplitude less than the threshold for causing contractions of skeletal muscle and cardiac muscle, and subsequent pulses have amplitudes greater than said threshold.

14. The apparatus of claim 13 wherein each succeeding initial pulse has a generally greater amplitude than the preceding pulses.

15. The apparatus of claim 1 wherein the series of individual pulses is such that, at cardiac threshold (i.e. when the pacing stimuli are adjusted to an amplitude just high enough to cause cardiac contractions), there is less skeletal muscle stimulation than would result using a continuous pulse having the same duration as the series of pulses.

16. The apparatus of claim 1 wherein the series of individual pulses is such that, at cardiac threshold (i.e. when the pacing stimuli are adjusted to an amplitude just high enough to cause cardiac contractions), there is less discomfort to the patient than would result using a continuous pulse having the same duration as the series of pulses.

17. A method of transcutaneously pacing the heart at a pacing rate, the method comprising the steps of:

generating electrical pacing stimuli;

delivering the stimuli to a patient through electrodes applied to the patient's chest;

wherein the pacing stimuli generated and delivered to the patient comprise a series of individual pulses.

18. The method of claim 17 wherein each series of pulses is capable, as a group, of causing a contraction of the heart, but each individual pulse is incapable, by itself, of causing such a contraction.

19. The method of claim 17 wherein said series of pulses extends for a duration of at least 5 msec.

20. The method of claim 17 wherein the duration of the individual pacing pulses averages less than 0.5 msec.

21. The method of claim 20 wherein said average pulse duration is less than 250 microseconds.

22. The method of claim 21 wherein said average pulse duration is less than 50 microseconds.

23. The method of either of claims 20, 21, or 22 wherein the duty cycle of said individual pulses is greater than 20%.

24. The method of claim 23 wherein the duty cycle of said individual pulses is greater than 50%.

25. The method of claim 17 wherein the amplitude of said pacing stimulus in the intervals between individual pulses is less than the pulse amplitude required for stimulating cardiac muscle if the pulse amplitude remained constant for the duration of the series of pulses.

26. The method of claim 23 wherein the average amplitudes of said series of individual pacing pulses rise from a first amplitude to a second amplitude.

27. The method of claim 26 wherein said first amplitude is less than the threshold for stimulation of skeletal muscle.

28. The method of claim 27 wherein said second amplitude is reached in not less than 2 pulses.

29. A method of transcutaneously pacing the heart at a pacing rate, the method comprising the steps of:

generating electrical pacing stimuli;

delivering the stimuli to a patient through electrodes applied to the patient's chest;

wherein the pacing stimuli generated and delivered to the patient comprise a plurality of pulses, with at least the initial pulse in each stimulus having an amplitude less than the threshold for causing contractions of skeletal muscle and cardiac muscle, and subsequent pulses have amplitudes greater than said threshold.

30. The method of claim 29 wherein each succeeding initial pulse has a generally greater amplitude than the preceding pulses.

31. The method of claim 17 wherein the series of individual pulses is such that, at cardiac threshold (i.e. when the pacing stimuli are adjusted to an amplitude just high enough to cause cardiac contractions), there is less skeletal muscle stimulation than would result using a continuous pulse having the same duration as the series of pulses.

32. The method of claim 17 wherein the series of individual pulses is such that, at cardiac threshold (i.e. when the pacing stimuli are adjusted to an amplitude just high enough to cause cardiac contractions), there is less discomfort to the patient than would result using a continuous pulse having the same duration as the series of pulses.

33. Apparatus for transcutaneously pacing the heart at a pacing rate, the apparatus comprising

stimuli generating circuitry for generating electrical stimuli, and

electrodes connected to the output of the stimuli generating circuitry for delivering the electrical stimuli to the patient,

wherein said stimuli generated and delivered to the patient include

pacing stimuli occurring generally at the pacing rate, and having a shape and amplitude capable of causing contractions of the cardiac muscle, and

background stimuli occurring at times other than said pacing stimuli, and having a shape and amplitude incapable of causing contractions of the cardiac muscle.

34. The apparatus of claim 33 wherein said background stimuli occur only at times other than said pacing stimuli.

35. The apparatus of claim 33 wherein each said background stimulus comprises a series of background pulses.

36. The apparatus of claim 35 wherein each said pacing stimulus comprises a series of pacing pulses.

37. The apparatus of claim 36 wherein the average amplitude of said background pulses is less than the average amplitude of said pacing stimuli.

38. The apparatus of claim 37 wherein the duty cycle of said background pulses is less than 80%.

39. The apparatus of claim 38 wherein said duty cycle is less than 50%.

40. The apparatus of claim 37 wherein said series of background pulses has an average current amplitude of less than 20 mA.

41. The apparatus of claim 40 wherein said series of background pulses has an average current amplitude of less than 10 mA.

42. The apparatus of claim 38 wherein each series of pulses is capable, as a group, of causing a contraction of the heart, but each individual pulse is incapable, by itself, of causing such a contraction.

43. The apparatus of claim 42 wherein the duration of the individual pacing pulses averages less than 0.5 msec.

44. The apparatus of claim 43 wherein the duty cycle of said individual pulses is at least 20%.

45. The apparatus of claim 43 wherein the amplitudes of said series of individual pacing pulses rise from a first amplitude to a second amplitude.

46. Electrodes for transcutaneous pacing, said electrodes comprising

a first electrical terminal for making a connection to an external source of electrical current,

a second electrical terminal for making a connection to an external source of electrical current,

a first skin-contacting region electrically connected to said first terminal of the electrode, and

a second skin-contacting region electrically insulated from said first region and spaced laterally from said first region and electrically connected to said second terminal of the electrode.

47. The electrodes of claim 46 wherein said first region laterally surrounds said second region.

48. The electrode of claim 47 wherein said second region is generally circular and said first region is generally annular.

49. A method of transcutaneously pacing the heart at a pacing rate, the method comprising the steps of:

generating electrical stimuli;

delivering the stimuli to a patient through electrodes applied to the patient's chest;

wherein the stimuli generated and delivered to the patient include

pacing stimuli occurring generally at the pacing rate, and having a shape and amplitude capable of causing contractions of the cardiac muscle, and

background stimuli occurring at times other than said pacing stimuli, and having a shape and amplitude incapable of causing contractions of the cardiac muscle.

50. The method of claim 49 wherein said background stimuli occur only at times other than said pacing stimuli.

51. The method of claim 49 wherein each said background stimulus comprises a series of background pulses.

52. The method of claim 51 wherein each said pacing stimulus comprises a series of pacing pulses.

53. The method of claim 52 wherein the average amplitude of said background pulses is less than the average amplitude of said pacing stimuli.

54. The method of claim 53 wherein the duty cycle of said background pulses is less than 80%.

55. The method of claim 53 wherein said duty cycle is less than 50%.

56. The method of claim 53 wherein said series of background pulses has an average current amplitude of less than 20 mA.

57. The method of claim 56 wherein said series of background pulses has an average current amplitude of less than 10 mA.

58. The method of claim 54 wherein each series of pulses is capable, as a group, of causing a contraction of the heart, but each individual pulse is incapable, by itself, of causing such a contraction.

59. The method of claim 58 wherein the duration of the individual pacing pulses averages less than 0.5 msec.

60. The method of claim 59 wherein the duty cycle of said individual pulses is at least 20%.

61. The method of claim 59 wherein the amplitudes of said series of individual pacing pulses rise from a first amplitude to a second amplitude.

62. The method of claim 49 wherein the pacing and background stimuli are delivered through electrodes whose configurations are different during the pacing and background stimulation intervals so that the background stimuli are, for the most part, not delivered through the chest but the pacing stimuli are delivered through the chest.

63. The method of claim 62 wherein one electrode is applied to either side of the chest, and the electrodes each comprise

a first electrical terminal for making a connection to an external source of electrical current,

a second electrical terminal for making a connection to an external source of electrical current,

a first skin-contacting region electrically connected to said first terminal of the electrode, and

a second skin-contacting region electrically insulated from said first region and spaced laterally from said first region and electrically connected to said second terminal of the electrode, and wherein

the background stimuli are passed between the first and second skin-contacting regions of the same electrode, and the pacing stimuli are passed between from one electrode to the other electrode.

64. The electrodes of claim 63 wherein said first region laterally surrounds said second region.

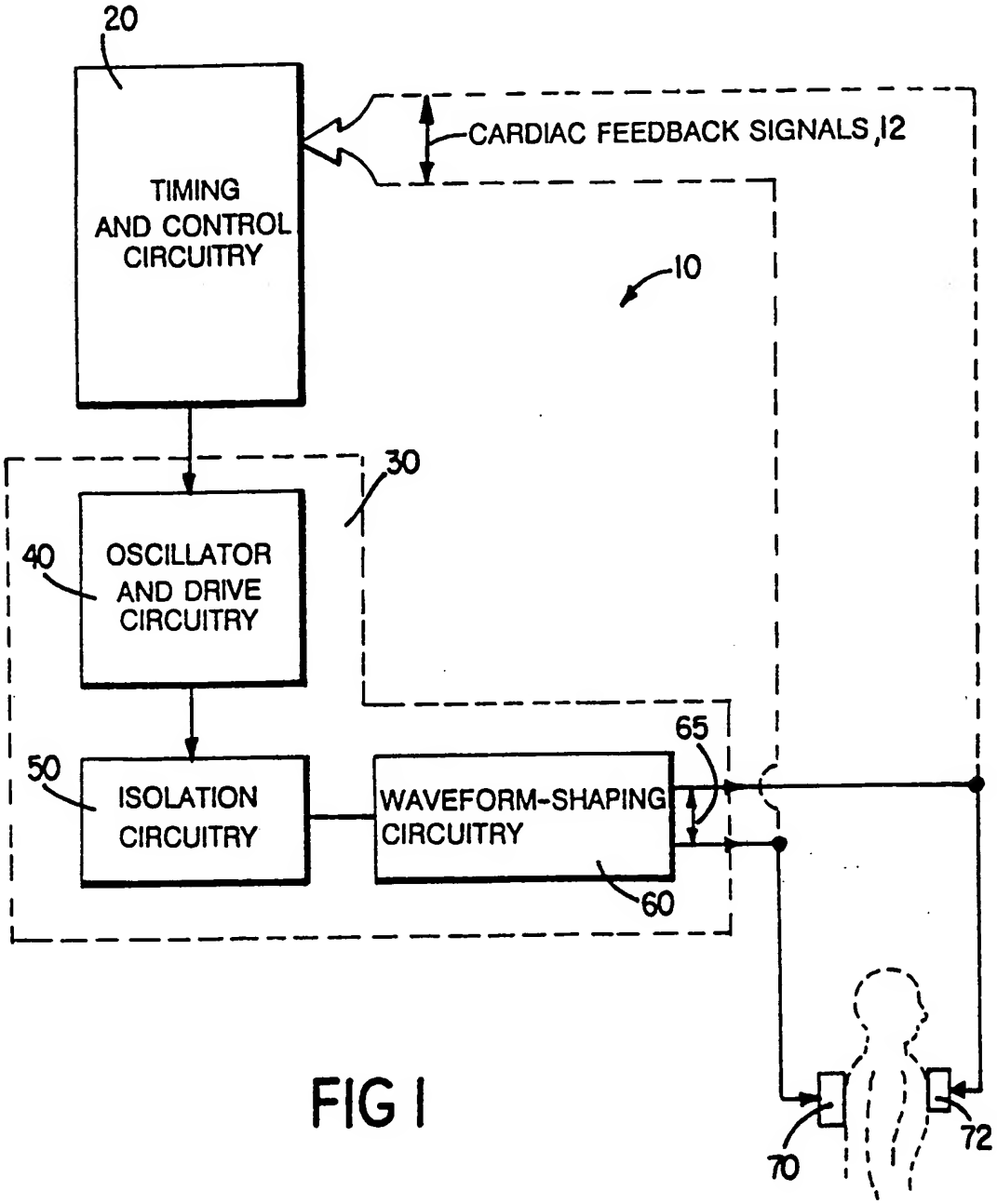
20
TIMING AND CONTROL CIRCUITRY
CARDIAC FEEDBACK SIGNALS ,12
10
30
40
OSCILLATOR AND DRIVE CIRCUITRY
50
ISOLATION CIRCUITRY
WAVEFORM-SHAPING CIRCUITRY
65
60
70
72

FIG 1

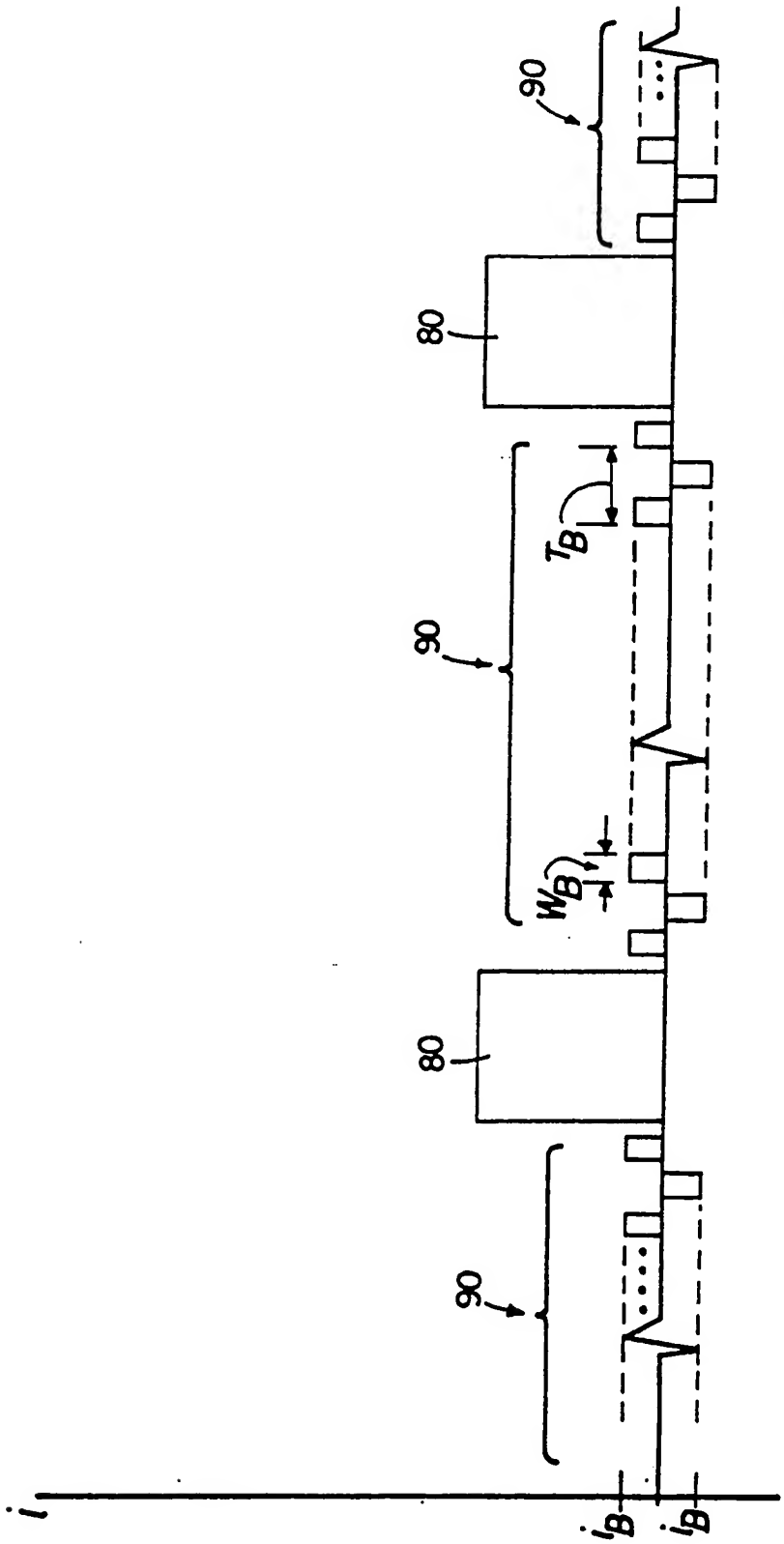

FIG.2

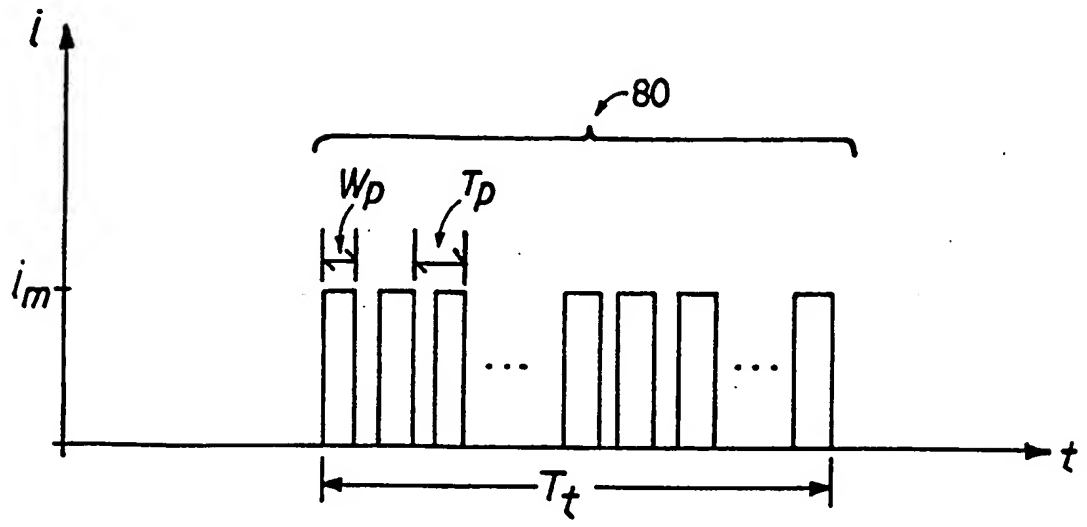

FIG. 3A

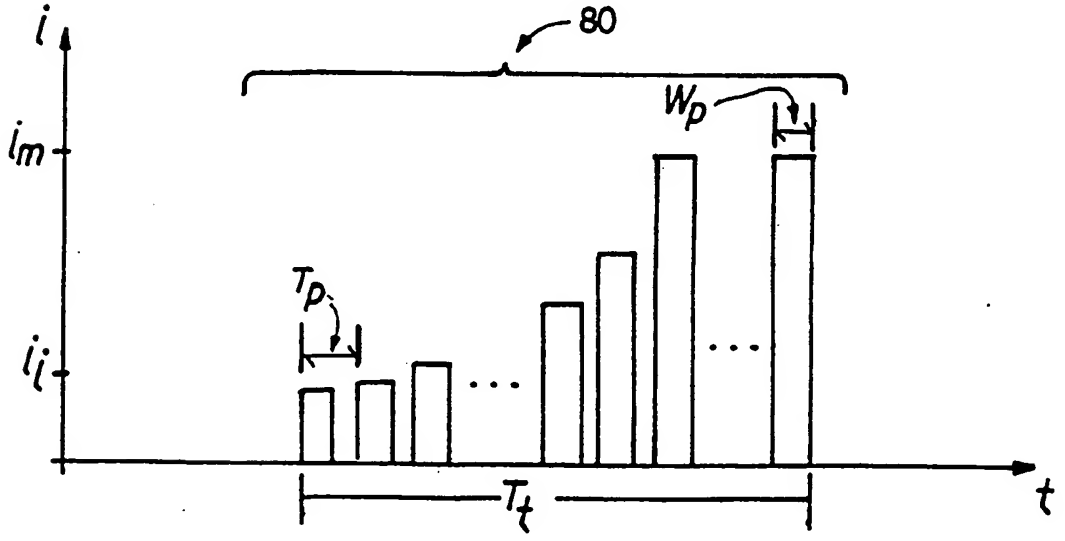

FIG. 3B

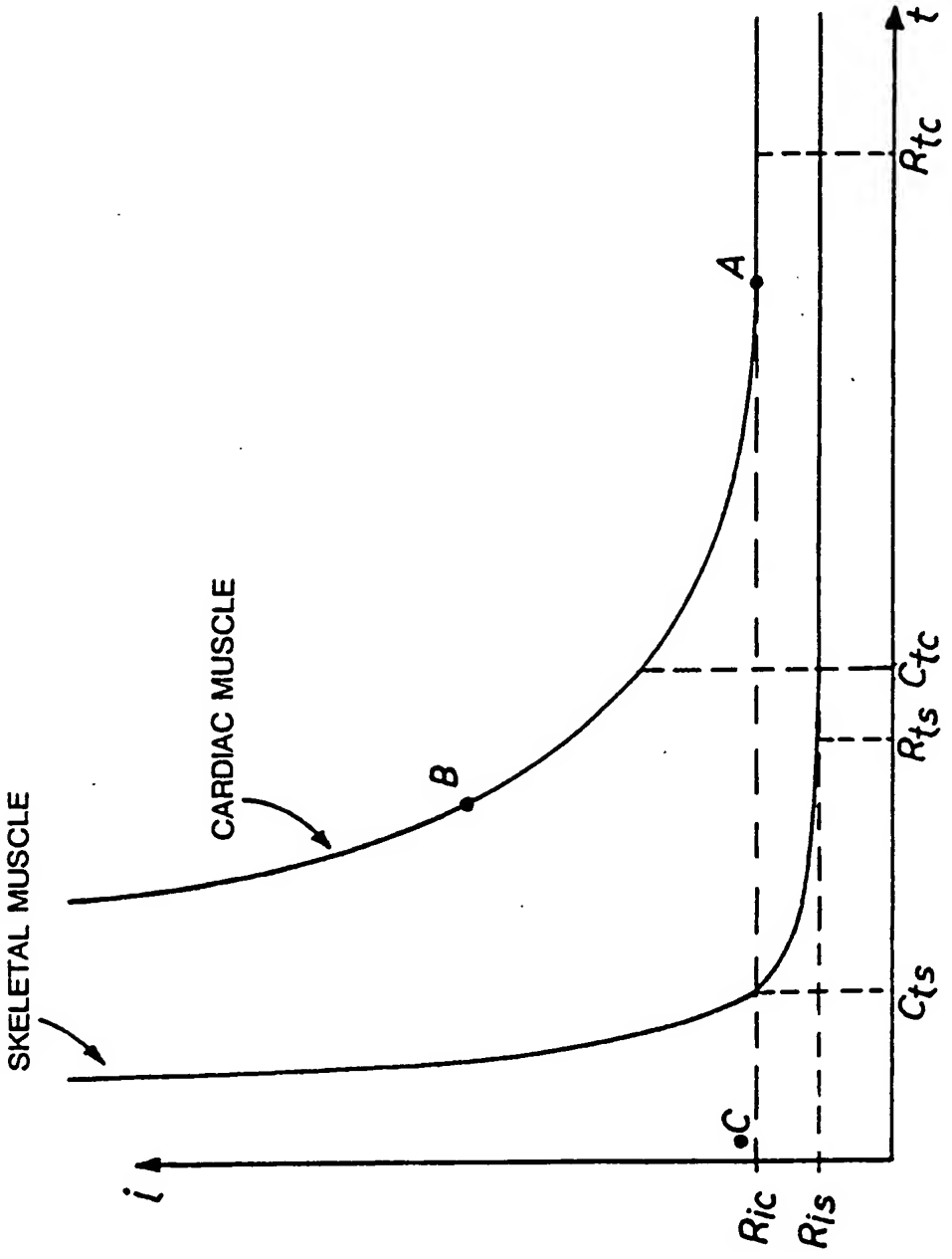
t
A
B
C
CARDIAC MUSCLE
SKELETAL MUSCLE
i
Rtc
Ctc
Rts
Cts
Ric
Ris

FIG. 4

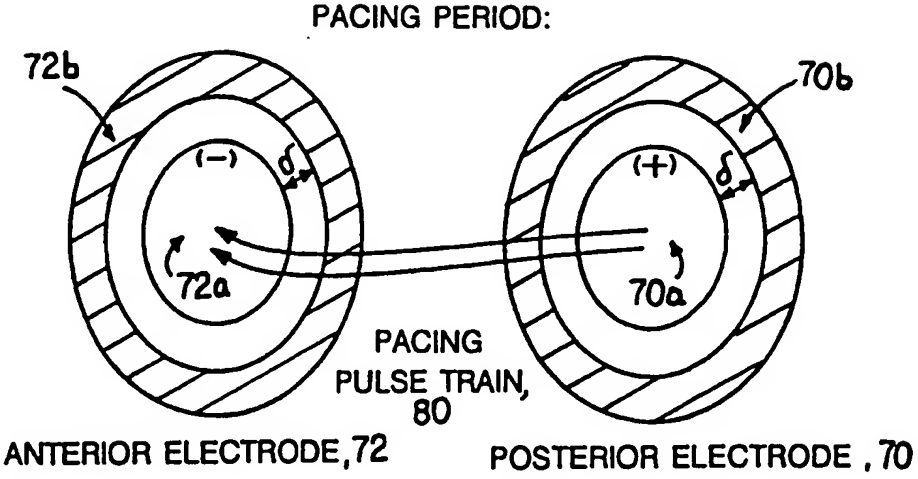
PACING PERIOD:
72b
70b
(−)
δ
(+)
δ
72a
70a
PACING
PULSE TRAIN,
80
ANTERIOR ELECTRODE, 72
POSTERIOR ELECTRODE , 70

FIG. 5A

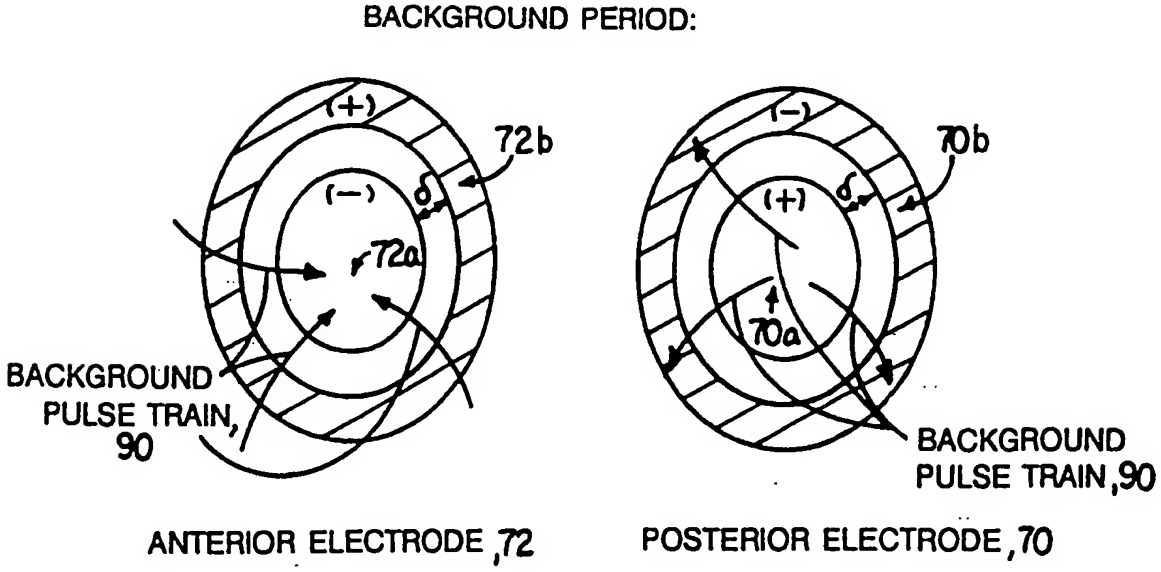
BACKGROUND PERIOD:
(+)
72b
(−)
δ
72a
BACKGROUND
PULSE TRAIN,
90
(−)
70b
(+)
δ
70a
BACKGROUND
PULSE TRAIN, 90
ANTERIOR ELECTRODE, 72
POSTERIOR ELECTRODE, 70

FIG. 5B

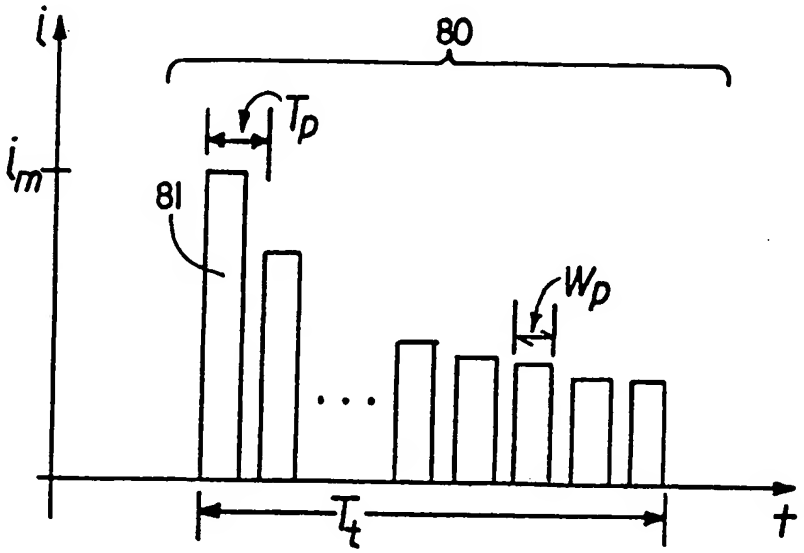

FIG. 6A

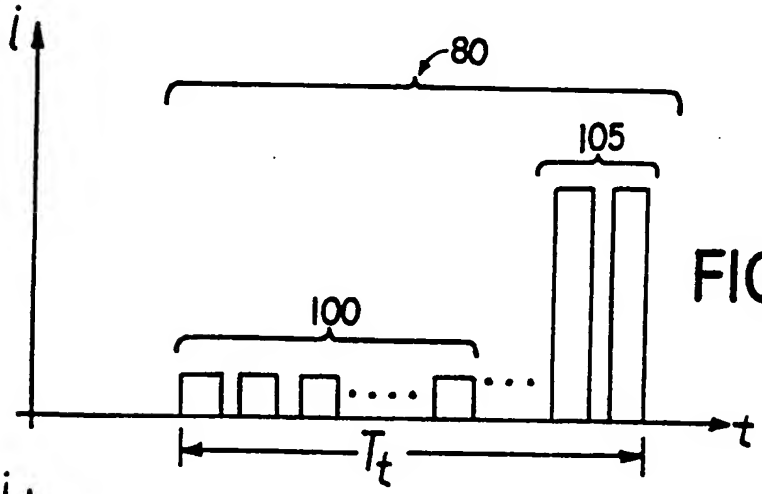

FIG.6B

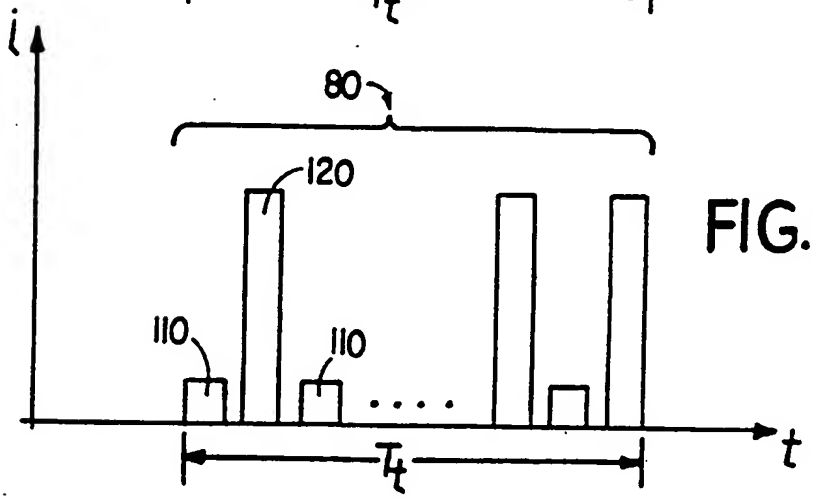

FIG.6C

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/04972

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61N 1/36 U.S. CL: 128/419.0PG

II FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U. S.	128/419.0PG, 419.00D, 421

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X Y	US, A, 4,787,389 (TARJAN) 29 NOVEMBER 1988 See entire document.	1, 2, 13-16 3-12
X Y	US, A, 4,222,386 (SMOLNIKOV) 16 SEPTEMBER 1980 See entire document.	1-9 10-16
Y	US, A, 4,580,570 (SARRELL) 08 APRIL 1986 See entire document.	17-32
X	US, A, 3,050,695 (DUVALL) 21 AUGUST 1962 See entire document.	1, 17
X	US, A, 4,177,817 (BEVILACQUA) 11 DECEMBER 1979 See entire document.	46

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

05 FEBRUARY 1992

Date of Mailing of this International Search Report

28 FEB 1992

International Searching Authority

ISA/US

Signature of Authorized Officer

NGUYEN T. NGOC
INTERNATIONAL DIVISION
for SCOTT GETZOW

Form PCT/ISA/210 (second sheet) (Rev.11-87)